



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

## CHARTER

### ADVISORY COMMITTEE ON BLOOD AND TISSUE SAFETY AND AVAILABILITY

#### AUTHORITY

The Advisory Committee on Blood and Tissue Safety and Availability (hereafter referred to as the Committee or ACBTSA) is authorized under 42 U.S.C. 217a, Section 222 of the Public Health Service (PHS) Act, as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App), which sets forth standards for the formation and use of advisory committees.

#### OBJECTIVES AND SCOPE OF ACTIVITIES

The Secretary is responsible under Sections 301, 351, and 361 of the PHS Act, as amended (42 U.S.C. 241, 262, 264), and various provisions of the Federal Food, Drugs and Cosmetic Act (21 U.S.C. 301 *et seq.*) for issuing and enforcing regulations concerning the collection, preparation, and distribution of blood, blood products, tissues and organs; for issuing and enforcing regulations related to the transmission of communicable diseases; and for carrying out research in health fields including diseases involving these products.

The ACBTSA will advise, assist, consult with, and make policy recommendations to the Secretary, through the Assistant Secretary for Health, regarding these broad responsibilities related to the safety of blood, blood products, organs and tissues, as further delineated under Description of Duties. For solid organs and blood stem cells, the Committee's work will be limited to policy issues related to donor derived infectious disease complications of transplantation.

#### DESCRIPTION OF DUTIES

The Committee will provide advice on a range of policy issues to include:

- (1) identification of public health issues through surveillance of blood and tissue safety issues with national biovigilance data tools;
- (2) identification of public health issues that affect availability of blood, blood products, and tissues;
- (3) broad public health, ethical and legal issues related to the safety of blood, blood products, and tissues;
- (4) the impact of various economic factors (e.g., product cost and supply) on safety and availability of blood, blood products, and tissues;
- (5) risk communications related to blood transfusion and tissue transplantation; and
- (6) identification of infectious disease transmission issues for blood, organs, blood stem cells and tissues.

## **AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS**

The Committee will provide advice to the Secretary, through the Assistant Secretary for Health.

## **SUPPORT**

Management and support services for Committee activities will be provided by staff from within the Office of HIV/AIDS and Infectious Disease Policy, which is a program office within Office of the Assistant Secretary for Health (OASH). The OASH is a staff division within Office of the Secretary in the Department of Health and Human Services.

## **ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS**

Estimated annual cost for operating the Committee, including compensation and travel expenses for members, but excluding staff support, is \$92,500. Estimated person years of staff support required is 2.0, at an estimated annual cost of \$315,000.

## **DESIGNATED FEDERAL OFFICER (DFO)**

The Senior Advisor for Blood and Tissue Policy in the OASH Office of HIV/AIDS and Infectious Disease Policy will serve as the DFO for the Committee. In the event that the DFO cannot fulfill the responsibilities associated with this position for the Committee, then the Alternate DFO shall serve in this capacity and carry out the assigned duties for this position.

The DFO will schedule and approve all meetings of the Committee and any respective subcommittee meetings that are to be held. The DFO will prepare and approve all meeting agendas. Development of the meeting agenda can be done in collaboration with the Committee chair(s), and, when it is deemed appropriate, the chairs of any respective subcommittees of the Committee. The DFO will attend all meetings of the Committee and any respective subcommittees that are established to assist the Committee. The DFO also has authority to adjourn meetings, when it is determined to be in the public interest, and can be directed by the Assistant Secretary for Health or designee to chair meetings of the Committee.

## **ESTIMATED NUMBER AND FREQUENCY OF MEETINGS**

The Committee will meet not less than once a year. Meetings will be open to the public, except as determined otherwise by the Secretary or other official to whom authority has been delegated, in keeping with the guidelines under Government in the Sunshine Act, 5 U.S.C. 552b(c). The public will be given notification about Committee meetings that are scheduled to be held; notices to announce the meetings will be published in the *Federal Register*. Meetings will be conducted and records of the proceedings will be kept, as required by applicable laws and Departmental policies. A quorum of not less than one-half of the membership is required for the ACBTSA to meet to conduct business.

When it is determined by the Secretary, or other official to whom authority has been delegated, that a meeting will be closed or partially closed to the public, in accordance with stipulations of Government in the Sunshine Act, 5 U.S.C. 552b(c), then a report will be prepared that includes, at a minimum, a list of the members and their business addresses, the ACBTSA's function, date and place of the meeting, and a summary of the Committee's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

## **DURATION**

Continuing.

## **TERMINATION**

Unless renewed by appropriate action, the Committee will be terminated two years from the date the charter is filed.

## **MEMBERSHIP AND DESIGNATION**

The Committee will consist of not more than 23 voting members, who represent a diverse group of patient advocates, subject matter experts, and health professionals. One or more of these voting members will be selected to serve as Chair, with an option for Vice Chair or Co-Chairs. The Committee members will be invited to serve for overlapping terms of up to four years. Terms of more than two years are contingent upon renewal of the Committee's charter by appropriate action prior to its expiration. A member may serve no more than 180 days after the expiration of the member's term, if a successor has not taken office.

The Committee composition will include 14 public members, who will be selected from state and local organizations, patient advocacy groups, provider organizations, academic researchers, ethicists, physicians, surgeons, scientists, risk communication experts, consumer advocates, and from among communities of persons who are frequent recipients of blood or blood products or who have received tissues or organs. While this document sets no prescribed formula for distribution of membership, every attempt will be made for equal and diverse representation. The public voting members will be classified as special government employees (SGEs) and are subject to government ethics rules.

The Committee will also include 9 voting representative members who are designated to serve by the blood, tissue and organ professional organizations and/or business sectors. These representative members will be selected from the AABB, American Association of Tissue Banks (AATB), the Eye Bank Association of America, the Association of Organ Procurement Organization (AOPO), and one of either the American National Red Cross (ARC) or America's Blood Centers (ABC) on a rotating basis. The Committee composition can include additional representation from either the plasma protein fraction community or a trade organization; a manufacturer of blood, plasma, or other tissue/organ test kits; a manufacturer of blood, plasma or

other tissue/organ equipment; a major hospital organization or a major hospital accreditation organization. Where more than one company produces a specified product or process, representatives from those companies will rotate on the same schedule as public members. All voting members of the Committee will be selected by the Secretary or designee.

The Committee shall also include nine non-voting *ex-officio* members to represent the Centers for Disease Control and Prevention; the Centers for Medicare and Medicaid Services; the Food and Drug Administration for which representation will be provided by the Office of Blood Research and Review (OBRR) and the Office of Cellular, Tissue and Gene Therapies (OCTGT); the Health Resources and Services Administration, which will include representation from the Chair of the Advisory Committee on Organ Transplantation; the National Institutes of Health (NIH) for which representation will be provided by the National Heart, Lung, and Blood Institute and the NIH Clinical Center; the Department of Defense; and the Department of Veterans Affairs. Other federal departments/agencies will be invited to participate as non-voting *ex-officio* members, as the Secretary or designee deem necessary, to effectively carry out the Committee's function.

The voting public members will be paid at a rate not to exceed \$200.00 per day, plus per diem and any applicable travel expenses, as authorized by Section 5703, Title 5, U.S.C., for persons employed intermittently in the government service. Members who serve as representatives of a particular interest group or business sector will serve without compensation, pursuant to advance written agreement, but may be allowed per diem and any applicable expenses for all government-directed travel. Members who are officers or employees of the United States government shall not receive compensation for their services on the Committee.

## **SUBCOMMITTEES**

In carrying out its function, the Committee may establish subcommittees, with approval of the Secretary or designee, to provide assistance in carrying out work associated with the mission of the Committee. The subcommittees will be composed of members of the parent committee and/or non-member individuals who have expertise and knowledge regarding the topics and issues that are pertinent to the mission of the Committee. The established subcommittees may consider issues in accordance with the charge of the Committee, and will, as appropriate, make reports to the ACBTSA for consideration. The established subcommittees may not report directly to the Secretary or another federal official unless there is specific statutory authority for such reporting. The Department Committee Management Officer will be notified upon establishment of each subcommittee, and will be given information regarding its name, membership, function, cost, and estimated frequency of meetings.

## **RECORDKEEPING**

Records of the Committee and any established subcommittees will be handled in accordance with General Records Schedule 6.2, Federal Advisory Committee Records or other approved agency

records disposition schedule. Applicable records will be made available to the public for inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.


**FILING DATE**

October 9, 2016

**APPROVED:**

**OCT 05 2016**

Date

  
Sylvia M. Burwell